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June 13, 2017

VIA ECF
Hon. Douglas E. Arpert, U.S.M.J.
United States District Court, District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *Fenwick, et al. v. Ranbaxy Laboratories, LTD., et al.*, No. 3:12-cv-7354 (PGS)

Dear Judge Arpert:

This firm, together with Kirkland & Ellis LLP, represents Defendants in the above-captioned matter. This letter responds to Plaintiffs' letter to the Court, which they filed in the afternoon of Monday, June 12. (Dkt. 110, the "Letter.")

Plaintiffs' Letter contains numerous inaccuracies and omissions with respect to Defendants' document production and the discovery process to date. Defendants will not belabor each point, but do feel compelled to respond to several of the points that Plaintiffs raise: (1) the fact that Plaintiffs apparently intend to ask the Court for an extension of the third-party discovery deadline—even though they have no basis to do so, particularly because Plaintiffs have apparently engaged in only minimal third-party discovery to date; (2) Plaintiffs' backdoor attempt at seeking reconsideration of the Court's May 15, 2017 order, which denied Plaintiffs' request for an extension of discovery deadlines despite their contentions (which they now make again) that Defendants had improperly withheld documents; (3) Plaintiffs' baseless contentions that the thousands of documents that Defendants have produced are somehow "useless" and "cannot be deciphered," even though Defendants produced documents as they were stored in the course of business; and (4) the scheduling of the deposition of the fifth and last named Plaintiff, given her medical conditions and the current deadlines.

For reasons detailed below, Defendants believe there is no reason to extend any of the deadlines in the current Scheduling Order—much less the "good cause" that Rule 16(b)(4) requires for such an extension.[1] Nor is there any reason to expedite the rescheduling of a status conference, as Plaintiffs request. Defendants thus respectfully request that the conference with Your Honor be rescheduled for a date in either the week of July 24 or July 31, as noted in Defendants' June 11 submission. (Dkt. 109.) Because Plaintiffs have not yet formally sought a modification of the current scheduling order, Defendants also reserve all rights to formally object to any such request in subsequent briefing.

[1] *See* Fed. R. Civ. P. 16(b)(4) ("A schedule may be modified only for good cause and with the judge's consent.").

I. There Is No Basis for Any Extension of the Third-Party Discovery Deadline.

Plaintiffs write that they "need additional time to conduct the third-party discovery from the 35 companies that received the recalled pills." (Letter at 3.) There is no basis whatsoever for Plaintiffs' request to extend this deadline, much less the "good cause" required by Rule 16(b)(4).

To begin with, the deadline for third-party discovery in this case has already been extended before—by six months. The initial deadline to complete all discovery was December 22, 2016. (Mar. 16, 2016 Pretrial Scheduling Order, Dkt. 71 at 2.) Following a November 9, 2016 status conference with the Court, the parties' submission of briefing on unresolved discovery disputes, and another conference on January 9, 2017, the Court extended the third-party discovery deadline until June 30, 2017. (Jan. 11, 2017 Revised Scheduling Order, Dkt. 90 at 1.)

Another status conference then took place on April 10, 2017. In their pre-conference submission, Plaintiffs advised the Court that "[i]t is unknown whether the non-party discovery can be completed by June 30th." (Dkt. 99 at 2.) During the conference, the parties discussed discovery deadlines with the Court. Following that conference, the Court issued a revised scheduling order on April 11, 2017. (Dkt. 101.) Notably, while the Court extended the deadline for party discovery until June 2, it ***did not*** further extend the third-party discovery deadline. (*Id.* at 1 ("The deadline to complete third party discovery remains June 30, 2017.").) Finally, in their May 3, 2017 submission made after Defendants' supplemental document production, Plaintiffs then asked for another extension "of 60 days for all of the dates in the Scheduling Order." (Dkt. 102 at 3.) Defendants opposed Plaintiffs' request (Dkt. 103) and the Court denied it on May 15. (Dkt. 105.)

So, the deadline for third-party discovery has already been extended from December 22, 2016 until June 30, 2017; the current June 30, 2017 deadline has been in place since January 11, 2017; and the Court has already denied Plaintiffs' prior request for an extension. Without even acknowledging ***any*** of this, Plaintiffs now write that they need still more time for third-party discovery. The only two reasons Plaintiffs cite in support are: (1) a supposed "need to obtain the information in a useful format from the defendants' computer systems about the returned bottles"; and (2) that "the discovery from the 35 companies is time-consuming, although manageable." (Letter at 3.) Neither argument has any merit.

First, Plaintiffs' contention that they need more information "about the returned bottles" (*id.*) ignores the fact that Plaintiffs have had documents regarding recall information for 35 consignees that had received the Atorvastatin at issue ***since August 2016***.[2] Plaintiffs have thus had documents for ten

[2] These documents include, for example: (1) an Excel spreadsheet which details the amount of the recalled product that had been distributed to the consignees (with this information broken down by, among other things, drug NDC number and product strength (e.g., 10mg pills, 20 mg pills, etc.)), RANBAXY_FEN0000132; (2) a compilation of Recall Response Forms that Ranbaxy received from consignees, which set forth the amount of the recalled Atorvastatin the consignee had and would return to Ranbaxy (with this information broken down by product strength, lot #, NDC #, and pill bottle size), RANBAXY_FEN0000559; and (3) a summary of information Ranbaxy had collected from consignees

months that (among other things) identify the consignees who received the recalled product, show the amount of product that was distributed to them, and show the amount of product those consignees had and would return. To the extent Plaintiffs needed further information from these 35 consignees, there is no reason that Plaintiffs could not have subpoenaed them for information months ago—rather than wait until the last moment to ask for yet another extension after the Court has already denied their request.

Second, Plaintiffs had asserted in an April 7, 2017 submission to the Court that they needed certain modifications to the protective order "to be able to move forward with the non-party investigation and discovery[.]" (Dkt. 99 at 3.) As Defendants advised Plaintiffs in their April 7 response, Defendants had previously "set forth the conditions under which they would not object to Plaintiffs' use of [certain of Defendants'] documents with non-parties . . . in their March 6, 2017 submission to the Court." (Dkt. 100 at 2.) In that same response, Defendants also made clear that they were agreeable to Plaintiffs using those documents for informal non-party discovery on such conditions. (*Id.* ("To be clear, as Defendants previously advised Plaintiffs, Defendants do not object to Plaintiffs' use of documents with non-parties on the conditions set forth in the [March 6] submission.").) So, Plaintiffs also cannot argue that they could not have pursued third-party discovery sooner—particularly because Defendants still do not understand why Plaintiffs have any need to use Defendants' documents for such discovery, instead of simply subpoenaing the 35 consignees at issue.

Third, Plaintiffs' argument that discovery from 35 companies "is time-consuming" (*id.*) provides no basis for any extension in light of Plaintiffs' lack of diligence in pursuing third-party discovery to date. Indeed, Plaintiffs' statement that they have "***started*** our interaction with the 35 companies and some of the downstream retailers because of the time-pressure of the June 30th deadline" (*id.* (emphasis added)) suggests that despite knowing about the current deadline for months, Plaintiffs have ***only just now*** begun their third-party discovery efforts. And those efforts appear to have been minimal indeed. As of this filing, Defendants have not been served with any copies of subpoenas from Plaintiffs to any of these 35 companies—which presumably means that Plaintiffs have not even issued a single such subpoena, even though the third-party discovery deadline is now less than three weeks away. Plaintiffs have known for months (if not more) that Ranbaxy had distributed the recalled Atorvastatin to many different consignees, and Plaintiffs have likewise known for months who those consignees are. That Plaintiffs have apparently not even begun the process of subpoenaing documents from these consignees—despite now acknowledging that "third-party discovery ***is very important*** in this case because [plaintiffs] need to obtain a lot of information from the 35 companies to whom the defendants shipped the recalled pills" (*id.* at 1 (emphasis added))—is inexplicable. Plaintiffs' lack of diligence not only belies their assertion that they are "entitled to [more] time to conduct" third-party discovery (*id.* at 3); it means that there is plainly no good cause for a (yet another) extension.[3]

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through the Recall Response Forms, which Ranbaxy then provided to the FDA, RANBAXY_FEN0000149.

[3] *See, e.g.*, *Marlowe Patent Holdings LLC v. Dice Electronics, LLC*, 293 F.R.D. 688, 700-701 (D.N.J. 2013) ("pursuant to Fed. R. Civ. P. 16(b)(4), a schedule may be modified only for good cause and with the judge's consent," and "determination of good cause depends on the diligence of the moving party where the moving party has the burden of demonstrating that despite its diligence, it could not

II. Plaintiffs' Accusations that Defendants Improperly Withheld Documents Are Baseless.

Plaintiffs also argue that Defendants supposedly "improperly withheld a substantial number of important information and documents." (Letter at 2.) These are the same arguments that Plaintiffs had raised after document production was completed at the end of April. (*See* Dkt. 102 at 1, 2 (arguing that Defendants' supposed "withholding of documents that should have been disclosed is improper," and that these documents "should have been disclosed previously").) Defendants previously responded to these arguments and the Court has already ruled on them. To recap briefly, the documents that Plaintiffs contend should have been disclosed sooner were produced after the parties disagreed over what (if any) further documents should be produced by both sides, and after Defendants retrieved the files of several additional custodians and undertook further document review following the Court's ruling resolving those disputes; moreover, those documents were largely cumulative of previously-produced ones. (*See generally* Dkt. 103.) After reviewing submissions on this issue from both sides, the Court denied Plaintiffs' request for an extension of discovery deadlines on May 15, 2017. (Dkt. 105.)

Plaintiffs' contention that an extension is warranted due to supposed issues with Defendants' document production is thus really an untimely request for reconsideration of the Court's May 15 Order. But Plaintiffs do not even argue that they could meet the high standard for reconsideration[4]—nor could they. Plaintiffs still do nothing to refute the point Defendants raised the last time this issue was before the Court: that "many of these documents are duplicative of information that Defendants had previously produced and/or are cumulative of information that was summarized in the reports that Defendants had provided to the FDA—reports which Plaintiffs have now had for months." (Dkt. 103 at 2.)

The only specific example Plaintiffs now raise is that Defendants produced additional Recall Response Forms. (Letter at 2.) Plaintiffs do not identify what new Recall Response Forms were produced by Defendants (*see id.*); but to be clear, Defendants ***have*** previously produced (in August 2016) a compilation of completed Recall Response Forms from consignees (RANBAXY_FEN0000559) as well as a summary of information from consignees' Recall Response Forms that Ranbaxy submitted

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reasonably have met the scheduling order deadline.") (citations, alterations, and quotation marks omitted) (Arpert, M.J.); *Chancellor v. Pottsgrove School Dist.*, 501 F. Supp. 2d 695, 701 (E.D. Pa. 2007) ("if the party was not diligent, there is no 'good cause' for modifying the scheduling order").

[4] *See* L.R. 7.1(i) (requiring motions for reconsideration to be "served and filed within 14 days after the entry of the order," unless otherwise provided by statute of rule, and requiring such motions to be accompanied by a "brief setting forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked"); *Delanoy v. Township of Ocean*, 2015 WL 2235103, at *2 (D.N.J. May 12, 2015) ("The standard for reargument is high and reconsideration is to be granted only sparingly," and a Rule 7.1(i) motion may be granted only upon showing of "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court issued its order; or (3) the need to correct a clear error of law or fact to prevent manifest injustice.") (citations and quotation marks omitted) (Arpert, M.J.).

to the FDA (RANBAXY_FEN0000149).[5] Plaintiffs do not identify what, if any, information may have been in the later-produced forms that Plaintiffs did not already have from Defendants' August 2016 production.

III. Defendants' Documents Are Not "Useless."

Plaintiffs also assert that the "documents that the defendants produced cannot be deciphered and is in a useless format." (Letter at 2.) It is unclear why Plaintiffs believe those documents are indecipherable and useless, particularly because Defendants produced responsive documents in the manner that they were kept in ordinary course of business—including the very same materials that Defendants had submitted to the FDA to keep it apprised about the recall process and status.

Far from producing "useless" documents, Defendants have also previously provided additional explanations regarding those documents, going beyond what the Federal Rules of Civil Procedure require. (*See* Dkt. 86, Defs.' Dec. 2, 2016 Letter to the Court, at 2 (advising the Court that "Defendants provided further clarification [to Plaintiffs], identifying the Bates numbers of documents containing responsive information and tying them to Plaintiffs' Interrogatories.").) Moreover, after Plaintiffs previously complained to the Court that Defendants' documents were difficult to understand, the Court gave Plaintiffs leave to serve additional interrogatories to ask about Defendants' documents and certain terms in those documents. Plaintiffs did so, and Defendants responded to those interrogatories.

But despite having all of this additional information, Plaintiffs still argue that Defendants' documents are confusing. They now contend, for example, that some "spreadsheets about the returned bottles of pills identify 'Ranbax' as the returning entity for tens of thousands of the returned bottles." (*Id.*) The Letter does not identify what spreadsheets Plaintiffs mean in particular; during depositions, however, Plaintiffs' counsel questioned one of Defendants' employees on this topic with respect to the RANBAXY_FEN0000870 spreadsheet. (*See* Ex. B, Excerpts from June 2, 2017 Dep. of Syad Qadry, at 122:8-123:7.) But as Mr. Qadry testified, "this [spreadsheet] is Inmar's report" (Inmar is a third-party vendor who assisted Ranbaxy with the recall); thus, he could not "answer those questions" because "[t]hose are Inmar nomenclature and their terminology." (*Id.* at 123:8-18; *see also id.* at 124:1-6 ("What I'm saying is this is Inmar's report, so they are using terminologies under some titles, title terminology. I don't know what their basis is to have those terms as titles.").) Additional discovery from Ranbaxy is not going to help Plaintiffs understand a report that was prepared by a non-Ranbaxy entity, particularly

[5] Plaintiffs also argue that when asked about additional recall response forms at a deposition, one of Defendants' witnesses "agreed that the additional forms were either withheld or the initial search was poorly done." (Letter at 2.) To the extent Plaintiffs may be referring to the deposition of Mr. Richard Lewellyn, he also testified that he did not know how the search for recall response forms was conducted and did not know whether response forms from 2012 were readily available. (Ex. A, Excerpts from May 30, 2017 Dep. of Richard Lewellyn, at 297:15-298:3 (testifying, in response to questions about "recall response forms," that "I don't know who provided it or the method that they used to provide it."); *id.* at 299:25-300:6 ("The recall response forms, to my knowledge, are maintained on the CLS web portal that I have access to. However, I do not know if I can access 2012 today, without their assistance. I don't know when they archive. I don't know how far back I'm able to go, I guess is what I'm telling you.").)

where Defendants' employee has already testified that he cannot answer questions about such third-party reports. If Plaintiffs needed additional information from Inmar, they should have subpoenaed and/or deposed Inmar before the end of third-party discovery. And whatever Plaintiffs' confusion about this particular spreadsheet may be, the fact is that Defendants have produced multiple other documents with recall-related information regarding the 35 consignees who had received the recalled Atorvastatin—and have also previously provided Plaintiffs with additional information about Defendants' documents, including through interrogatory responses.

Finally, to the extent Plaintiffs may argue that they are entitled to have Defendants create ***new*** and customized documents regarding the recall because Plaintiffs are not satisfied with the documents that Defendants have available and had previously produced (as Plaintiffs appear to contend, *see* Letter at 3), that is not the law. *See, e.g.*, *Alexander v. F.B.I.*, 194 F.R.D. 305, 310 (D.D.C. 2000) ("Rule 34 only requires a party to produce documents that are ***already*** in existence," and "[a] party is not required to prepare, or cause to be prepared, new documents solely for their production.") (citations omitted, emphasis added); *Net Navigation Sys., LLC v. Cisco Sys., Inc.*, 2013 WL 12156380, at *2 (E.D. Tex. Sept. 5, 2013) (noting, in denying a motion to compel, that "[a] party is not required to prepare new documents solely for their production in litigation."); *Belanus v. Dutton*, 2017 WL 1102727, at *17 (D. Mont. Mar. 23, 2017) ("A party responding to a Rule 34 document request cannot be compelled to prepare or create new documents."). Thus, any extension of the discovery deadlines here would be not only unwarranted but also futile, because Plaintiffs are not entitled to new documents they demand.

IV. Scheduling of the Deposition of the Fifth Plaintiff.

Defendants have now deposed four of the five named Plaintiffs. (Letter at 2.) Plaintiffs note that the deposition of the fifth Plaintiff has not been "conducted because she had medical problems involving a heart condition" which restricts her ability to travel, and they write that "defendants initially refused to schedule her deposition after June 2nd, but they just asked about her availability to be deposed so they may have changed their position." (*Id.* at 2 n.1.) This is incorrect, as Defendants did not refuse to schedule this deposition after June 2nd. Instead, upon learning about this Plaintiff's medical issues, Defendants advised Plaintiffs' counsel that they would accommodate her travel restrictions by flying out to Texas to depose her. On May 31 (two days before the June 2 fact discovery cut-off), Defendants asked whether Plaintiffs' counsel had a date certain in the next week or two on which he could make this Plaintiff available for a deposition. On June 9, in hopes of having further clarity on this issue before the status conference, Defendants then asked for another update on this Plaintiff's availability to be deposed. Plaintiffs advised that they were uncertain when they could make her available for a deposition.

As Defendants' counsel advised Plaintiffs' counsel before, Defendants are mindful of Plaintiff's medical issues and remain willing to be flexible, but the parties are also operating under Court deadlines. Indeed, the deadline for fact discovery has already passed. If the fifth Plaintiff's medical condition precludes her from being deposed within a reasonable time of close of fact discovery (for example, within two weeks after the June 2 deadline, or June 16), then she should not continue as a named Plaintiff in this case—particularly because four named Plaintiffs (all of whom have now been deposed) will still remain.

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This litigation has been proceeding for a long time and has now gone through multiple schedule extensions; it is now time to bring it to a close without any further delays. Defendants believe that no further extensions are warranted and are ready to continue moving forward under the current schedule. Defendants also believe that there is no reason to expedite the rescheduling of a status conference; thus, Defendants respectfully request that the conference with Your Honor be rescheduled for a date in either the week of July 24 or July 31. Defendants also reserve their rights to further object to any formal requests by Plaintiffs for any discovery extensions.

Respectfully,

/s/ Michael E. Patunas

Michael E. Patunas

cc: All Counsel of Record (Via ECF)